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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,982	10/24/2005	Gregory Durand	033339/292131	9612

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
06/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,982	DURAND ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/5/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The disclosure is objected to because of the following informalities: Page 1 of the specification fails to state that this case is a 371 of PCT/FR03/03335. Also, the section titled "Brief Description of the Drawings" is missing.

Appropriate correction is required.

Upon further search and consideration, the election of species requirement of February 7, 2008 is hereby withdrawn and all the claims in the case have been examined on the merits.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the variable X as set forth in claims 2-4, for the variable Y being oxygen, for the variable Y' being -O-C=O, –NH-C=0, -NH-C(=O)-NH-, -O-C (=O)-NH, O or S, does not reasonably provide enablement for the variables as set forth in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims encompass an immense number of species.

For example, the term "aminoderivatives of monosaccharide" encompasses lincomycins, kanamycins, gentamicins. The disclosure of a single specific amino sugar

i.e. glucosamine is not adequate to support the general terminology "amino derivatives of monosaccharides". Also, for example, the term "polysaccharide" (claim 1) encompasses starch, cellulose, heparin, hyaluronic acid, chitin, agarose, etc. The only examples set forth in the specification are disaccharides i.e. sucrose and lactobionamide (page 6 of the specification, lines 23-26). The examples of two specific disaccharides does not provide an adequate support for the terminology "polysaccharide" which is not limited to any number of sugar moieties.

The variables Y and Y' are not limited to any number of carbon atoms and encompass chains of more than 100 carbon atoms.

(B) The level of predictability in the art.

It is well known in the pharmaceutical art that even a small change in the structure of a chemical compound. For example, there is a good reason to doubt that a compound of formula (I) of claim 1, wherein X is a peptide chain will have the same activity as compound herein X is a monosaccharide.

(C) The existence of working examples.

All working examples are limited to only four specific compounds, all of which X is a monosaccharide.

(D) The specification discloses four specific compounds which are useful in protecting cells from apoptosis (pages18-19 of the specification). However, this guidance is not commensurate with the full scope of the claimed invention.

(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori, which compounds will be active from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Claims 9-11 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the claimed compounds as antioxidants, does not reasonably provide enablement for preventing the effects of free radicals (Claim 9), to prevent or treat the pathological conditions linked to oxidative stress and to the formation of oxygen-containing free species (claim 10), for preventing or treating immune and inflammatory diseases, the ischemia-reperfusion syndrome, atherosclerosis, Alzheimer's disease, Parkinson's disease, lesions due to UV and ionizing radiations, Huntington's disease, cancers and cellular aging (claim 11) and for preventing and/or treating the effects of aging (claim 13). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

Claims 9-11 and 13 encompass prevention of diseases i.e. the claims encompass administration of the claimed compound to a healthy host and preventing the same from ever getting a disease. The claims also encompass the treatment of

such diseases as atherosclerosis, Alzheimer's disease, Parkinson's disease, lesions, Huntington's disease, cancer, cellular aging and the effects of aging.

(B) The state of the prior art.

Phenybutyl nitron compositions are known to be useful for the treatment of oxidative tissue damage.

(C) The level of predictability in the art.

A person having ordinary skill in the art at the time the invention was made would not have been able to predict on a limited amount of evidence presented in the specification directed to testing four specific compounds for their ability to trap free radical species and assessing the neuroprotective efficacy on nerve-muscle cocultures, for the treatment of which specific disease or conditions, the claimed methods and compositions would be useful.

(D) The amount of direction provided by the inventor.

The specification discloses four specific compounds which have antioxidant, antiapoptic activity and neuroprotective efficacy on nerve-muscle.

However, this guidance is not commensurate with the full scope of the claimed invention.

(E) The existence of working examples.

The working examples are limited to testing four specific compounds for their ability to trap free radical species, antioxidant ability, antiapoptotic activity and neuroprotective efficacy on nerve-muscle.

(F) The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which specific compounds will be active in the prevention or treatment of which specific diseases or conditions from the test data set forth in the specification, an extraordinary amount of trial and error experimentation is required to identify the active compounds and their ability to treat or prevent the diseases or conditions encompassed by the present claims.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 and 14 provide for the use of a compound as claimed in claim 1, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-11 and 14 are is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623